

May 20, 2020 VIA ELECTRONIC MAIL regulations.gov

Seema Verma Administrator Centers for Medicare and Medicaid Services P.O. Box 8013 Baltimore, MD 21244-1850

Re: CMS-5529-P, Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing

Dear Ms. Verma:

On behalf of the Adventist Heath Policy Association (AHPA), we appreciate the opportunity to comment on the Medicare Program: Comprehensive Care for Joint Replacement (CJR) Model Three-Year Extension and Changes to Episode Definition and Pricing proposed rule. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 90 hospitals in 16 states.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. Due to the difference among our hospitals and their geographic locations, our comments provide an objective and sound policy voice that work for health care as a whole.

Our comments on the CJR Model Three-Year Extension proposed rule come at a time when we as a global community are facing the COVID-19 pandemic. Our health system joins the rest of the nation's providers to make every effort to ensure the adequate care for every patent, protect our staff and safeguard the general health of our community. In addition to our comments on this proposed rule, we ask CMS to consider the impact that the COVID-19 pandemic will have on the current CJR model and the policies in the proposed rule. As we rise to meet the challenge this pandemic brings, our everyday operations are being disrupted by efforts to mitigate and manage this immediate threat. Therefore, we are providing recommendations on what CMS can do to alleviate the negative impacts on the model as well as comments on the following issue areas in the proposed rule:

- Episode Definition
- Target Price Calculation
- Reconciliation
 - o Additional Episode-Level Risk Adjustment
 - Changes to Methodology for Determining the High Episode Spending Cap Amount at Reconciliation
 - o Changes to Trend Factor Calculations
 - o Changes to Composite Quality Score Adjustment
- Three-Year Extension

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- Participant Notification
- Quality Measures and Reporting
- Waivers
- ASC Models

Recommendations to Mitigate Impact of COVID-19

AHPA believes that the impact of the COVID-19 pandemic on the current CJR model and the policies in this proposed rule will be considerable. The health care industry's priorities are shifting to increase hospital capacity to prepare for COVID-19 cases across our markets and potential surges of patients if the economy reopens. Everyday operations, such as elective surgeries and post-acute services are being disrupted, impacting how CJR beneficiaries are managed. As a result, providers participating in CJR and other Alternative Payment Models (APMs) face the following risks:

- An increase in COVID-19 related hospitalizations, emergency department visits and intensive care unit stays, which can raise the expenditure per patient.
- Suspension of elective surgical cases, causing a higher level of risk adjustment in the current performance.
- Limited in-person care, which can lead to delayed care for high-risk patients and potential future hospitalizations.
- Medication shortages that can cause delay in services and hospitalizations
- Attribution of only sicker, higher-cost patients in APMs due to healthier patients avoiding physician visits.
- Post-acute services interrupted due to COVID-19 outbreaks, limited PPE and testing shortages, which cause challenges to provide discharge planning and placement of patients in post-acute settings.

The consequences of the above-mentioned risks may lead to the following:

- Additional downside risk due to increased costs and target prices being set at a pre-pandemic baseline.
- Sicker populations due to the suspension of elective surgeries, an increase in COVID-19 cases, delay in care for vulnerable high-risk patients and disruptions in their post-acute and outpatient care management.
- Possible penalties if CMS does not adjust the target prices in future performance years.

In light of the ongoing COVID-19 pandemic and the issues referenced above, AHPA recommends that CMS suspends performance year 5. This will help to alleviate burden on providers as we continue to respond to the threat of COVID-19. CMS will need to determine how long a suspension is appropriate because there will be a time period where only parts of the country will allow elective surgeries and others will not. Facilities in areas with restrictions will be at a disadvantage in alternative payment models because they will not be able to operate at normal capacity. We recommend that the model is extended for the same duration that CMS deems it appropriate to suspend the model during the COVID-19 pandemic.

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If this policy is *not* adopted, we recommend that CMS excludes episodes that do *not* meet the model target price. These clinical episodes would not be included in performance period spending or in episode-based quality measure scores to reduce their impact on the long-term model performance.

If CMS does *not* adopt either of the two abovementioned policies, we would then recommend that CMS eliminates the downside risk in the CJR model. We believe that providers should not be penalized if our ability to effectively manage patients is impacted due to our efforts to address the COVID-19 pandemic.

Additionally, we recommend that the target prices should be adjusted to account for the impact of the pandemic in the health care delivery system regardless of which policy is adopted. The cost of episodes will be affected by COVID-19 cases, and this should not be reflected in future years of the model. Target prices should either exclude the costs of episodes during the pandemic or be adjusted to mitigate the impact on future performance years.

Episode Definition

CMS proposes to revise the definition of an "episode of care" in the CJR model to include outpatient Total Knee Arthroplasties (TKAs) and Total Hip Arthroplasty (THA) procedures. Since TKAs were removed from the Inpatient Only (IPO) list, CMS states that, nationally, 25 percent of all TKA procedures are now performed in the outpatient setting. Due to the rise of these procedures in the outpatient setting, CMS believes that these procedures should be included in the proposed CJR model extension.

While the number of TKAs and THAs performed in the outpatient setting has increased overall, the increase varies widely across hospitals. The number of complex cases in a market drive the overall case mix, as more complex patients need to stay in the inpatient setting and less complex cases can go to the outpatient setting. The complexity of cases can be driven by factors including elderly populations in an area, comorbidities, and other demographic factors. These can impact participant hospitals' ability to adapt to the proposed changes in the model.

If this policy is finalized, AHPA asks that CMS provides outpatient cost data to participant hospitals. Participant hospitals do not have access to the full cost of care for Medicare beneficiaries in the outpatient setting. This information would help providers better understand beneficiaries' needs and how to meet those needs more cost-effectively. Without the cost data, it will be difficult to understand the impact of the variable case mix on cost.

Target Price Calculation

To calculate the target price for the extension period, CMS proposes using only one year of the most recently available data instead of the three most recent years as the baseline period. According to CMS, concerns about having insufficient episode volume is mitigated by moving toward regional pricing for model years four and five. The Agency also believes that using one year of data will provide a better picture of spending patterns during the performance period.

AHPA commends CMS' efforts to improve the accuracy of the baseline prices; however, we disagree that moving to one year of data will better reflect spending patterns. AHPA recommends keeping three-years of data as the baseline to reduce any unforeseen variability in the target prices.

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Using one year of data makes the target price more susceptible to any disruptions in the market. For example, the COVID-19 pandemic has resulted in patients having restricted access to medical services. This is due to providers focusing on COVID-19 patients and minimizing the risk of exposure for other patients. This makes it more difficult for providers to manage the chronic diseases of beneficiaries and could consequently lead to higher costs that do not reflect normal spending patterns. Other short-term disruptions in the market could affect future target prices and providers' ability to manage their beneficiaries' care. Particularly, if some areas in a proposed region experience a surge in COVID-19 cases while other areas do not, the regional pricing model the CMS is proposing would be a less valid way to adjust target pricing. Therefore, keeping three years of baseline data will help minimize the impact of any short-term disruption in the market.

Additionally, AHPA recommends that CJR, BPCI Advanced and ACO Lower Extremity Joint Replacement (LEJR) beneficiaries be excluded from the baseline calculations. We believe that the target price should be based on the expenditure for non-Alternative Payment Model (APM) patients. This way the cost of the non-managed patients can be compared to the cost of managed patients. In the current calculation, the better the performance of an APM, the lower the target price will be driven down due to these beneficiaries being included in the target price. This takes away from the amount of saving that participants can earn that that offset the high cost episodes of sick patients.

Reconciliation

Additional Episode-Level Risk Adjustment

CMS theorizes that while outpatient TKA procedures will be less costly than inpatient procedures, the new blended payment rate would average out the differences in cost. However, CMS acknowledges that hospitals do not usually have the same inpatient and outpatient case mix. To remedy this, CMS proposes to create an episode-specific adjustment for each target price to account for the varying case mix. AHPA requests that CMS clarifies how it will calculate the proposed episode-specific adjustment.

CMS also proposes to update the reconciliation calculation by adjusting the target price using the Hierarchical Condition Categories' (HCC) condition count and beneficiaries' ages. The HCC considers the number of comorbidities a patient may have, such as diabetes and obesity. Table 4 of the proposed rule outlines the risk adjustment factor multiplier for the age group and the number of HCCs a beneficiary may have. While most of the multipliers would increase the target price for a beneficiary, those in the 65 to 74 age group with zero or one HCC have a multiplier of slightly less than one, which would lower the target price. Nearly 50 percent of our CJR patients fall within the 65-74 age bracket. Based on internal analysis of our BPCI-Advanced LEJR episodes, 72 percent of the patients aged 65-74 have HCC score of zero or one. This would lower their respective target price compared to the regional average when using the less than one multiplier.

AHPA applauds CMS' efforts to provide risk adjustment for beneficiaries, as underlying comorbidities of individuals have a significant impact on the complexity and cost of care. We request that CMS clarifies the timeframe that it will be using to count the number of HCCs a beneficiary has. This will give providers a better understanding of how those comorbidities are being captured.

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Additionally, AHPA requests that CMS starts providing HCC data in the current model year before finalizing the proposed rule. CJR participants currently do not have HCC information for their patient population. Therefore, participants are at a disadvantage in fully understanding the implications of the proposed risk adjustment methodology. AHPA also recommends that the risk factor multipliers do not go lower than one. The purpose of this multiplier is to reduce the need for a high episode cap due to it being raised to the 99th percentile of historical costs. However, a multiplier of less than one penalizes providers because it lowers the target price that was set by previous spending patterns.

Changes to Methodology for Determining the High Episode Spending Cap Amount at Reconciliation Due to more episodes being capped than anticipated, CMS proposes to raise the high episode costs cap from two standard deviations above the mean to the 99th percentile amount within each region. This will result in more case having higher expenditures before they are capped. AHPA recommends that CMS sets the stop loss and stop gain at 10 percent, the same as performance year 3, to account for these higher expenditures being introduced.

Changes to Trend Factor Calculations

CMS proposes to remove the national trend factor update and replace it with a new region-specific, market trend adjustment factor. This market trend adjustment is designed to account for changes to prospective payment systems and fee schedules and the actual changes in episode costs between the baseline and the market.

AHPA does *not* support the adoption of a market trend factor as it would result in significant uncertainty for hospitals. This methodology would effectively establish a retrospective target price based on market trends. CJR participants do not have access to sufficient data sources to help determine these trends, making it difficult to anticipate changes in the market. Additionally, calculations at a regional, DRG and fracture status level could introduce more variability and make prices more susceptible to market disruptions than a national trend factor.

Changes to Composite Quality Score Adjustment

CMS proposes to reduce the discount factor based on a participant's composite quality score. For hospitals with good quality performance, a 1.5-percentage point reduction would be applied to the 3 percent discount factor. Hospitals with excellent quality performance would receive a 3-percentage point reduction to the 3 percent discount factor, effectively eliminating it. CMS believes that a more generous composite quality score is appropriate because hospitals will be at more financial risk during performance years six through eight.

AHPA supports the percentage point reduction to the discount factor based on the composite quality score.

Three-Year Extension

CMS originally proposed in this rule to begin the CJR extension model for an additional three years after performance year five. In more recently released proposed rule, Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC), performance year five is

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proposed to be extended for an additional three months. The changes in this proposed rule will apply to participant hospitals in the 34 mandatory Metropolitan Statistical Areas (MSAs), but not for hospitals who are in the 33 voluntary MSAs who previously opted into the program. Designated rural hospitals and low volume hospitals in the 34 mandatory MSAs are exempted from this proposal.

With the proposed three-month extension to performance year 5, AHPA requests that CMS provides more clarify on how this will impact the start date for this proposed rule. AHPA additionally requests that CMS clarifies what criteria would qualify a hospital as a low volume hospital in the 34 mandatory MSAs. This would assist hospitals in determining whether they will continue to participate in the model.

Participant Notification

CMS proposes that CJR participants must provide beneficiaries with detailed notices of their inclusion in the CJR model and any potential financial liability associated with non-covered services.

AHPA believes that patients should be equipped with the information necessary to keep them engaged and make well-informed decisions about their care. However, in the outpatient setting, there is a narrower opportunity to provide participant notifications as patients do not come into the facility until the day of their procedure.

AHPA recommends that doctors be allowed to provide participant notifications before the surgery instead of the CJR participating facility. We also recommend that CMS creates one notification letter for all advanced APMs, including BPCI Advanced. We believe that this will be less confusing for beneficiaries, as they currently receive significant amount of paperwork. A single notice would also help streamline the patient notification process and help alleviate some of the administrative burden placed on providers.

Quality Measures and Reporting

CMS proposes to apply the current Complications and HCAHPS measures performance periods to model years six through eight for both inpatient and outpatient procedures. Additionally, CMS proposes to increase the Patient Reported Outcomes (PRO) threshold requirements for successful data submission, as outlined in Table 5 of the proposed rule.

AHPA recommends that CMS creates additional quality metrics that would apply to the outpatient setting. The current Complications and HCAHPS measures that CMS proposes to apply to the outpatient setting only use inpatient data. Therefore, these measures would not reflect the quality of outpatient TKA and THA procedures. Using the readmission rate and Excess Days in Acute Care measures may better capture quality in the outpatient setting.

AHPA also recommends that the requirements for a successful submission should not go as high as 100 percent for PRO measures. AHPA further recommends that CMS implements the reporting thresholds used in performance year three. PRO data collection is burdensome for providers, especially in the post-operative setting, and requires a large amount of resources. If the threshold is too high, CJR participants may choose to forgo the two points given for a successful submission and divert those resources elsewhere in the model. This would greatly impact CMS' ability to collect PRO data that

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could be beneficial to beneficiaries. We believe that the proposed CMS thresholds are unrealistic, and the thresholds from performance year three are more feasible for a hospital to achieve. The thresholds set in performance year three were 70 percent or greater or 100 or more eligible procedures for pre-operation collection and 60 percent or greater or 75 eligible procedures for post-operation collection. Additionally, since there has not been any substantial information or analysis on the PRO measure data shared, we feel that there is minimal return on our investment to collect this data.

We also recommend that CMS adopts an alternative policy to base the number of points that a hospital would receive for PROs on the percentage of responses they collect. For example, if a provider collects 60 percent of PROs, they would only receive 60 percent of the available points. AHPA believes that this system would help incentivize providers to collect more PROs while rewarding them for the work that they do.

Waivers

CMS proposes to apply the waiver for the Skilled Nursing Facility (SNF) Three-Day rule to beneficiaries in the outpatient setting.

AHPA does not believe that this waiver should be applied in the outpatient setting. Facilities performing outpatient procedures should be sending beneficiaries to home health or therapy because these cases should be less complex and require less intensive post-acute care. We also recommend making this an indicator of quality and implementing penalties for providers that send beneficiaries to SNFs after an outpatient procedure.

ASC Models

CMS seeks comments on a new LEJR focused model that would include ASCs. Due to the lower complexity of procedures being performed in ASCs, it should be easier to project the cost of care. Therefore, potential models for ASCs could include a bundled payment program. AHPA believes that there is an opportunity for ASCs to perform in a value-based model, but it should not be introduced until there is more reliable data on the incorporation of outpatient TKAs. Additionally, this model should not be introduced until there are quality measures created specifically for outpatient orthopedic services. These measures should account for days spent in an emergency department, admission in an observation unit or an unplanned admission to the hospital after a procedure in the outpatient setting.

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Conclusion

We welcome the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact me at Carlyle.Walton@AdventistHealthPolicy.org or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,

Carlyle Walton, FACHE

President

Adventist Health Policy Association